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CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC			LASTRA, DANIEL	
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Please find below and/or attached an Office communication concerning this application or proceeding.

<u>`</u>		Application No.	Annliant(a)			
<b>,</b>		Application No.	Applicant(s)			
Office Action Summary		10/674,904	KOST ET AL.			
		Examiner	Art Unit			
		DANIEL LASTRA	3622			
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Status	,					
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	Responsive to communication(s) filed on <u>31 A</u>		•			
2a)∐	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
	closed in accordance with the practice under t	ex parte Quayle, 1935 C.D. 11, 4	453 O.G. 213.			
Dispositi	ion of Claims					
4)🛛	4)⊠ Claim(s) <u>1-10,16-25,31-45 and 51-55</u> is/are pending in the application.					
	4a) Of the above claim(s) is/are withdrawn from consideration.					
	Claim(s) is/are allowed.					
6)🖂	Claim(s) 1-10,16-25,31-45 and 51-55 is/are re	jected.				
	Claim(s) is/are objected to.	•				
-	Claim(s) are subject to restriction and/o	or election requirement.				
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	The specification is objected to by the Examine					
10)	The drawing(s) filed on is/are: a) acc					
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	Replacement drawing sheet(s) including the correct					
11)	The oath or declaration is objected to by the Ex	xaminer. Note the attached Office	e Action or form PTO-152.			
Priority ι	ınder 35 U.S.C. § 119					
a)[	Acknowledgment is made of a claim for foreign All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Burea See the attached detailed Office action for a list	ts have been received. Is have been received in Applica rity documents have been receiv u (PCT Rule 17.2(a)).	ntion No ved in this National Stage			
Attachmen 1) ⊠ Notic 2) □ Notic 3) □ Infor		4)  Interview Summar Paper No(s)/Mail I 5)  Notice of Informal 6)  Other:	y (PTO-413). Date			

#### **DETAILED ACTION**

1. Claims 1-10, 16-25, 31-45 and 51-55 have been examined. Application 10/674,904 has a filing date 09/30/2003 and Claims Priority from Provisional Application 60/472,956 (05/22/2003).

#### Response to Amendment

2. In response to Advisory Action filed 08/16/2006, the Applicant filed an RCE on 08/31/2006, which amended claims 1, 16, 21 and 31.

## Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites "and without using a server in a medical office of the prescriber to monitor the activities of the prescriber". Nowhere, in Applicant's specification, said limitation is recited or explained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. Claim 1 recites "and without using a server in a medical office of the prescriber to monitor the activities of the prescriber". For purpose of art rejection, said limitation would be interpreted as allowing a prescriber to order drug samples online.

## Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 51-55 are rejected under 35 U.S.C. 102(b) as being anticipated by the Software MedManage which is described in the following articles RxCentric and MedManage (Dialog: File 610: 00483951), MedManage tracks troublesome pill samples (Dialog file 635:2075728), For consumers free samples are a virtual reality (Dialog file 9:02648296), Samples of the Future (Dialog file 9:02536449), MedManage Systems, Inc Names Cecil Kost President and CEO (Dialog file: 613:00743102) and MedManage Systems Enhances Online Drug Sample Voucher System for Physicians (Dialog file 16:08804082).

As per claim 1, <u>RxCentric and MedManage (Dialog: File 610: 00483951)</u> article teaches:

A computer-implemented system for promoting pharmaceutical drugs, comprising:

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a computer-readable set of brand rules for guiding a distribution of drug samples of a drug to cause one prescriber's drug sample availability and characteristics to be different from those of another prescriber (see paragraphs 1-6); and

a computer-implemented drug sample fulfillment platform that is Web-based for implementing the set of brand rules to allow a prescriber to obtain drug samples to dispense to a patient without the use of a sales representative and without using a server in a medical office of the prescriber to monitor the activities of the prescriber (see paragraphs 1-2).

As per claim 2, <u>For consumers free samples (Dialog file: 9: 02648296)</u> article teaches:

The system of Claim 1, wherein drug samples include physical samples (see paragraph 20).

As per claim 3, <u>For consumers free samples (Dialog file: 9: 02648296)</u> article teaches: The system of Claim 1, wherein drug samples include a pad of pre-printed vouchers (see paragraph 10).

As per claim 4, <u>For consumers free samples (Dialog file: 9: 02648296)</u> article teaches:

The system of Claim 1, wherein drug samples include a coupon printed in the office of the prescriber, which is networked to the drug sample fulfillment platform (see paragraph 8).

As per claim 5, <u>RxCentric and MedManage (Dialog: File 610: 00483951)</u> article teaches:

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The system of Claim 1, wherein the drug samples, which are in a printed form, are redeemable at a pharmacy, redeemed data being generated by the drug sample fulfillment platform for refining the brand rules so as to better guide distribution of the drug samples (see paragraph 8).

As per claim 6, <u>RxCentric and MedManage (Dialog: File 610: 00483951)</u> article teaches:

A system for distributing pharmaceutical drugs, comprising:

a drug sample fulfillment platform for accessing drug sample services (see paragraph 1); and

a first set of Web pages coupled to the drug sample fulfillment platform through which a prescriber can access the drug sample fulfillment platform to order drug samples if a set of brand rules which specify drug sample availability and characteristics for the prescriber permits the prescriber to access the drug sample fulfillment platform (see paragraphs 1-6).

As per claim 7, For consumers free samples (Dialog file: 9: 02648296) teaches:

The system of Claim 6, further comprising a second set of Web pages coupled to the drug sample fulfillment platform through which a sales representative can access the drug sample fulfillment platform (see paragraph 5). It is inherent that drug sales representative access the MedManage system for an e-detail session.

As per claim 8, <u>RxCentric and MedManage (Dialog: File 610: 00483951)</u> teaches:

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The system of Claim 6, further comprising a third set of Web pages coupled to the drug sample fulfillment platform through which a patient can access the drug sample fulfillment platform to obtain sample vouchers (see paragraph 1).

As per claim 9, For consumers free sample teaches:

The system of Claim 6, wherein the first set of Web pages display a list of drug samples available to the prescriber to order drug samples in a form selected from a group consisting of physical samples, pre-printed vouchers, and print on-demand coupons (see paragraph 11).

As per claim 10, RxCentric and MedManage (Dialog: File 610: 00483951) teaches:

The system of Claim 6, wherein the first set of Web pages display a list of the order history of the prescriber, the list including a date and a drug sample ordered by the prescriber (see paragraph 8). It is inherent that for the MedManage system to track sales efforts and collects sampling prescription data, the MedManage system has to display a list of an order history for said tracking.

As per claim 51, <u>RxCentric and MedManage (Dialog: File 610: 00483951)</u> article teaches:

The system of Claim 1, wherein said fulfillment platform comprising:

a pharma rules sample engines for performing personalization and intelligent brand rule implementation (see paragraphs 1-6);

a marketing sample engine for integrating with drug samples suppliers and Web portals for prescribers (see paragraphs 1-6) and

the pharma rules sample engine and the marketing sample engine being based on the set of brand rules and on a set of prescriber preferences (see paragraphs 1-6).

As per claim 52, <u>RxCentric and MedManage (Dialog: File 610: 00483951)</u> article teaches:

The system according of claim 51, wherein the marketing sample engine links the drug sample fulfillment platform to one or more suppliers and drug samples so as to inhibit the lack of supply of sample drugs desired by the prescriber or inhibit the inconsistent supply of drug samples desired by the prescriber (see paragraphs 1-6). MedManage system is linked to a plurality of pharmaceutical companies in order that prescriber order drug samples online.

As per claim 53, <u>RxCentric and MedManage (Dialog: File 610: 00483951)</u> article teaches:

The system according to claim 6, wherein said fulfillment platform implementing a set of brand rules under which pharmaceutical drug samples are distributed, wherein said brand rules include: product; allocation quantity; sample type selected from a group consisting of live samples, pre-printed samples and on-demand samples; and, drug strength (see paragraph 1-6). It is inherent that drug samples orders place online using the MedManage software have to include the products, quantities, type, drug strength, etc in order that the MedManage fulfill said order.

As per claim 54 MedManage tracks troublesome pill samples teaches:

The system according to claim 6, but fails to teach wherein said fulfillment platform implementing a set of brand rules for distributing pharmaceutical drug samples,

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said brand rules including timing considerations that are selected from a group consisting of sample offer time limits and rolling expiration dates for vouchers from either within or between brands for which a quantity of drug samples can be ordered (see <a href="MedManage tracks troublesome pill samples">MedManage tracks troublesome pill samples</a> paragraphs 11-15). MedManage system determines the different classes of medicines that are valid for a prescriber and it is inherent that there is a time frame for the validity of ordering drug samples, as drug samples have expiration date.

As per claim 55, <u>RxCentric and MedManage (Dialog: File 610: 00483951)</u> article teaches:

The system according to Claim 6, wherein said fulfillment platform comprising a pharma rules sample engine for implementation brand rules under which a prescriber may obtain drug samples, the pharma rules sample engine modifying the brand rules so as to change a quantity limit of drug samples to be distributed to the prescriber (see paragraph 6 "physician customized information").

## Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-20, 31-43 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over the software <u>MedManage</u> describes in the following articles <u>RxCentric and MedManage (Dialog: File 610: 00483951), MedManage tracks</u>

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troublesome pill samples (Dialog file 635:2075728), For consumers free samples are a virtual reality Dialog file 9:02648296), MedManage System enhances Online Drug Sample Voucher System for Physicians (Dialog file 16: 08804082) and Samples of the Future Dialog file 9:02536449).

As per claim 16, RxCentric and MedManage (Dialog: File 610: 00483951) teaches:

A drug sample fulfillment platform, comprising:

a drug sample Web site for mating with a portal that is selected from a group consisting of prescriber-oriented Web portals, an e-Detailing service, a Web site regarding a drug brand, and an online physician learning site (see paragraph 5-6); and

a request database for receiving requests of a prescriber through the drug sample Web site for drug samples, the request database responding to the prescriber by allowing the prescriber to print coupons or to print an order form for physical samples or pads of pre-printed vouchers if a set of brand rules allow the prescriber to receive drug samples in the form of print coupons, order forms for physical samples, or pads or pre-printed vouchers (see paragraphs 1-6), but does not expressly teach the drug sample fulfillment platform notifying the prescriber when the prescriber has not ordered drug samples for a certain amount of time. However, Official Notice is taken that it is old and well known in the prescription art that drug sales representative tend to visit prescribers that have not ordered drug samples for a certain amount of time in order to maintain a business relationship between said prescribers and the drug companies that said sales representative represents. Therefore, it would have been obvious to a person

of ordinary skill in the art at the time the application was made, to know that the MedManage system would alert prescribers that have not ordered drug samples for a certain amount of time in order to maintain a business relationship with said prescribers.

As per claim 17, Samples of the future (Dialog file: 9:02536449) teaches:

The drug sample fulfillment platform of Claim 16, wherein the request database receives claim information when a patient redeems a print coupon or a preprinted voucher for physical samples (see paragraph 10).

As per claim 18, <u>Samples of the future (Dialog file: 9:02536449)</u> teaches: The drug sample fulfillment platform of Claim 17, wherein the request database produces a first report accounting for the number of coupons or vouchers redeemed by patients of the prescriber (see paragraph 10).

As per claim 19, Samples of the future (Dialog file: 9:02536449) teaches:

The drug sample fulfillment platform of Claim 18, wherein the request database produces a second report correlating an allocation of drug samples of a drug to the prescriber with the number of prescriptions written by the prescriber relating to the drug (see paragraph 10).

As per claim 20, <u>RxCentric and MedManage (Dialog: File 610: 00483951)</u> teaches:

The drug sample fulfillment platform of Claim 19, wherein the request database produces a third report accounting for the monetary amount spent by a pharmaceutical company on a drug sample fulfillment program for a drug and a monetary amount

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associated with prescriptions written by the prescriber for the drug (see <u>RxCentric</u> paragraph 8 "track sales effort"; see <u>MedManage</u> tracks paragraph 15).

As per claim 21, <u>RxCentric and MedManage</u> and <u>MedManage tracks</u> troublesome pill samples (Dialog file 635:2075728) article teaches:

A networked system for ordering pharmaceutical sample drugs, comprising:

a drug sample fulfillment platform that comprises a drug sample Web site for mating with a Web portal when a prescriber selects a hyperlink (see paragraphs 1-6)

the drug sample Web site presenting a Web page including selectable options for the prescriber to order drug samples (see <a href="MedManage tracks troublesome pill samples">MedManage tracks troublesome pill samples</a> paragraph 15)

the time frame in which those drug samples are valid for the prescriber being specified by a set of brand rules (see <u>MedManage tracks troublesome pill samples</u> paragraphs 11-15). <u>MedManage</u> determines the different classes of medicines that are valid for a prescriber and it is inherent that there is a time frame for ordering drug samples, as drug samples have expiration date.

As per claim 22, For consumers free sample teaches:

The networked system of Claim 21, wherein the drug samples are in a form selected from a group consisting of physical samples and pre-printed vouchers (see paragraph 11).

As per claim 23, MedManage tracks troublesome pill samples teaches:

The networked system of Claim 21, wherein the selectable options of the Web page include a quantity for each drug sample, which is specifiable by the prescriber

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(see paragraph 15). It is inherent that for a prescribers to order drug samples online, said prescribers has to indicate the quantity of said order sample.

As per claim 24, MedManage tracks troublesome pill samples teaches:

The networked system of Claim 21, the selectable options of the Web page include a delivery location to which the drug samples will be shipped (see paragraph 15). It is inherent that for a drug manufacturer to deliver a drug sample order online by a prescriber, said order has to have the address of said prescriber.

As per claim 25, For consumers free samples teaches:

The networked system of Claim 21, wherein the selectable options of the Web page include an option for printing on-demand vouchers on a printer in the office of the prescriber (see paragraph 8).

As per claim 31, <u>RxCentric and MedManage (Dialog: File 610: 00483951)</u> and <u>MedManage System enhances Online Drug Sample (Dialog file 16: 08804082)</u> teaches:

A method for accessing a drug sample fulfillment platform, comprising: activating a link to access the drug sample fulfillment platform from a Web portal (see paragraphs 1-2);

creating a transaction that includes a prescriber identifier and a partner identifier (see <a href="MedManage system enhances">MedManage system enhances</a> paragraph 3 "register"). It is inherent that prescriber need to identify to access the online system in view of the prescription nature of sample drugs);

and mating a drug sample Web site to the Web portal allowing a prescriber to navigate and order drug samples only for drugs specified by a set of brand rules which

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include physical samples, pre-printed vouchers and print coupons (see paragraphs 1-2); and

RxCentric fails to teach shutting down redemptions through a pharmacy network by the drug sample fulfillment platform and disabling orders from drug samples in sample program that has expired. However, Official Notice is taken that it is old and well known in the promotion art that online orders placed in a website for unavailable items are disable by said website. It would have been obvious to person of ordinary skill in the art at the time the application was made, to know that online orders placed by prescribers for drug samples in a website would be disable by said website in view that it is old and well known to disable online orders for unavailable items.

As per claim 32, <u>RxCentric and MedManage (Dialog: File 610: 00483951)</u> article teaches:

The method of Claim 31, further comprising formatting a set of Web pages of the drug sample Web site prior to the act of mating to emulate the look and feel of the Web portal (paragraphs 1-2).

As per claim 33, <u>MedManage System enhances Online Drug Sample (Dialog file 16:08804082)</u> teaches:

The method of Claim 31, causing the prescriber to register if the prescriber identifier is not found in a request database (see paragraph 3).

As per claim 34, MedManage System enhances Online Drug Sample (Dialog file 16:08804082) and MedManage tracks troublesome pill samples teach:

The method of Claim 31, based on a segment to which the prescriber belongs, determining one or more of the following:

what drug samples that are available to the prescriber; a drug sample quantity limit that is available to the prescriber; a drug sample time limit in which the drug sample quantity limit is available; and the type of sample that is available to the prescriber (see <a href="MedManage System">MedManage System</a> paragraph 3; MedManage tracks paragraph 15). It is inherent that drug sample orders have time limits in view that drug samples have expiration dates.

As per claim 35, MedManage tracks troublesome pill samples teaches:

The method of Claim 34, receiving a selection for physical samples, the act of receiving including receiving a drug selection, a type of drug sample selection, a quantity of drug sample selection, and a delivery address (see paragraph 15).

As per claim 36, MedManage tracks troublesome pill samples teaches:

The method of Claim 35, receiving a print request to print an order form capturing the drug selection, the type of drug sample selection, the quantity of drug sample selection, and the delivery address (see paragraph 15).

As per claim 37, <u>RxCentric and MedManage (Dialog: File 610: 00483951)</u> article teaches:

The method of Claim 36, recording the requesting activities of the prescriber in a request database (see paragraph 8).

As per claim 38, For consumers free samples teaches:

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The method of Claim 34, receiving a selection for pre-printed vouchers or print coupons, the act of receiving including receiving a drug selection, and a quantity of coupons to be printed (see paragraph 5).

As per claim 39, For consumers free samples teaches:

The method of Claim 38, receiving a ship request to ship the pre-printed vouchers or a print request to print coupons capturing the drug selection (see paragraph 5).

As per claim 40, RxCentric teaches:

The method of Claim 39, recording the requesting activities of the prescriber in a request database (see paragraph 8).

As per claim 41, <u>Samples of the future</u> teaches:

The method of Claim 40, teach receiving a request to print a first report that lists registration data of the prescriber, the requesting activities of the prescriber, and the claim data from a claim processor that is indicative of redeemed pre-printed vouchers and print coupons at pharmacies (see paragraph 10).

As per claim 42, MedManage tracks troublesome pill samples teaches:

The method of Claim 40, receiving a request to print a second report that correlates drug samples of a drug distributed to the prescriber and with prescriptions written by the prescriber relating to the drug (see paragraph 11).

As per claim 43, RxCentric and MedManage (Dialog: File 610: 00483951) teaches:

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The method of Claim 40, receiving a request to print a third report that accounts for the return on investment for a monetary amount spent on a drug sample distribution program for a drug and the monetary amount received from prescriptions for the drug (see paragraph 8 "tracks sale efforts").

As per claim 45, <u>RxCentric and MedManage (Dialog: File 610: 00483951)</u> article teaches:

The method of Claim 40, refining the drug sample quantity limit of the prescriber based on the number of redemptions of pre-printed vouchers and print coupons associated with the prescriber (see paragraph 8 "tracks sale efforts").

6. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Software MedManage describes in the following articles RxCentric and MedManage (Dialog: File 610: 00483951), MedManage tracks troublesome pill samples (Dialog file 635:2075728), For consumers free samples are a virtual reality Dialog file 9:02648296), Samples of the Future Dialog file 9:02536449) and further in view of Feeney (US 2002/0032582)

As per claim 44, <u>RxCentric and MedManage (Dialog: File 610: 00483951)</u> article fails to teach:

The method of Claim 40, but fails to teach detecting fraud by comparing the drug sample quantity limit and the time frame in which the drug sample quantity limit is available to the prescriber and the claim data which is indicative of the number of preprinted vouchers and print coupons redeemed by patients. However, <u>Feeney</u> teaches a system that detects fraud with sample medication prescription (see <u>Feeney</u> paragraph

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284-285). Therefore, <u>MedManage</u> would have been motivated to add the feature of detecting fraud in coupon or voucher redemption, as taught by <u>Feeney</u> in view that coupon or voucher's fraud cost companies a lot of money without said companies receiving a return in the investment of said coupons.

### Response to Arguments

7. Applicant's arguments with respect to claims 1-10, 16-25, 31-45 and 51-55 have been considered but are moot in view of the new ground(s) of rejection. The Applicant argues that the Office needs to appreciate that Exhibit B discusses the flow of pieces of software that alone or in combination comprise a portion of the cited drug sample fulfillment platform and the Examiner is not taking the Affidavit at face value and merely poking at the imperfections of expressions in an engineering document. The Examiner answers that nowhere in Applicant's affidavit is mentioned anything about targeting or customizing drug samples, therefore, Applicant's affidavit has not established possession of either the whole invention or something falling within the claims. However, an issue of public use or on sale activity has been raised in this application. The article RxCentric and MedManage (Dialog: File 610: 00483951) is a publication dated March 20, 2001 that shows that Applicant disclosed his claimed invention of "allowing a prescriber to obtain drug samples to dispense to patient without the use of a sales representative and the customizing information of said drug samples for each prescriber", more than 1 year before the filing of the Applicant's application (05/22/03). Therefore, Applicant is barred from obtaining a patent. (In re Katz, 687 F.2d 450, 454, 215 USPQ 14, 17 (CCPA 1982). Furthermore because prior invention may not be

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established under 37 CFR 1.131 if the rejection is based upon a statutory bar (see

MPEP 715), additional information regarding this issue is required as follows: detailed

information on the product for sale or the specific public use of the product. Applicant is

reminded that failure to fully reply to this requirement for information will result in a

holding of abandonment.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to

applicant's disclosure:

Vouchers Replace Rx Samples in Bid to Stop Abuse (Dialog file 149:02920191)

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to DANIEL LASTRA whose telephone number is 571-272-

6720 and fax 571-273-6720. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, ERIC W. STAMBER can be reached on 571-272-6724. The official Fax

number is 571-273-8300.

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**Daniel Lastra** 

October 3, 2006

RAQUEL ALVAREZ

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PRIMARY EXAMINED